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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,204	01/20/2004	Kevin A. Thomas	MA9665P	2530

7590 03/15/2007
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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/762,204

Applicant(s)

THOMAS ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/19/04 9/1/05 7/21/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of applicant's Oath filed 10/1/2004 and IDS's filed 4/19/2004, 9/1/2005 and 7/21/2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20, 21 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to an implant comprising radiopaque markers comprising 30-70 volume percent barium sulfate and 70-30 volume percent polymer additive components. On page 7 of the instant specification it states that the composition comprises "a combination of 40-60 volume percent barium sulfate and 60-40 volume percent PAC", however there is no indication of the claimed percentages. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "radiopaque markers comprising 30-70 volume percent barium sulfate and 70-30 volume percent polymer additive components".

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites the limitation "barium sulfate" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Art-Based Rejections

6. It should be noted that the instant claims are product claims. There are many instances of product-by-process recitations, for example, "are sized to reduce visual obstruction of tissues surrounding the implant when the implant is placed in a patient" in claims 14 and 36 and "formed using an injection molding process" in claims 21 and 22. Determination of patentability is based on the product itself, not by the method in which it is made. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113).

7. It should further be noted that the instant claims contain intended use recitations such as "to permit visualization of a location of the implant without obscuring visualization of changes surrounding the implant when the implant is placed in a patient, and which does not interfere with other imaging modalities such as CT and MRI scans" in claim 1, "to allow for formation of the marker" in claim 3, and "to facilitate radiographic visualization of the implant when the implant is placed in the patient" in claim 30. Said limitations do not alone show patentable distinction. A recitation of intended use of the

claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 8, 30-32, 34-39 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Preissman (USPN 6,231,615 B1). Preissman discloses an enhanced visibility composition for implantation that can be readily observed under fluoroscopy or other imaging techniques such as X-ray, Ct, and MRI (abstract; col. 4, line 21). Said composition comprises a tissue implant material and radiopaque particles having a particle size between about 120 microns and 2200 microns (col. 2, lines 30-35). The tissue implant material is preferably, polymethyl methacrylate (e.g. nonresorbable), however alternative (resorbable) materials disclosed include hydroxyapatite, calcium phosphates, calcium sulfates, polymer based implants including polyglycolic acid and/or polylactic acid compounds and combinations thereof (col. 2, lines 45-59 and col. 6, lines 9-23; claim 7). Also, barium sulfate is disclosed as a radiopaque particle material (col. 2, lines 60). The composition is further disclosed as being injectable (col. 3, lines 34-37) and the composition may further contain additives (col. 4, lines 6-14). In addition,

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the drawings illustrate the composition's shape and form as well as the relationship between the implant material and particles. Thus, the disclosures of Preissman render the claims anticipated.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 3-7, 9-29, 33, 40-44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Preissman in view of Okada et al. (USPN 6,235,225 B1).

Preissman teaches the elements discussed above.

Preissman is silent to the radiopaque marker comprising a polymer additive. Okada teaches biocompatible implant materials comprising a binder and a raw material mixture of hydroxylapatite and calcium phosphate (abstract). In Example 2, Okada teaches a binding step that incorporates the particular binder, low-density polyethylene. Medium density polyethylene is also considered as a binder (col. 3, lines 64-67). One of ordinary skill in the art would have been motivated to include a binder such as low-density polyethylene or medium density polyethylene because Okada teaches that the binding step produces "very high strength" (col. 3, lines 23-25). A practitioner would reasonably expect an implant material having higher strength that would allow for easier handling and shaping (col. 3, lines 25-30). Thus, in Preissman, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include "a polymeric additive" or "binder" such as low-density polyethylene or medium density polyethylene as suggested by Okada.

Preissman is silent to the particular shape of the implantable composition being a sheet or a screw. One of ordinary skill in the art would have been motivated to change the shape of the implantable composition advanced by Preissman depending on the particular purpose of the implantable composition. Furthermore, the MPEP teaches that a change in shape is obvious absent persuasive evidence (see also MPEP 2144.04 (IV)(B)). A practitioner would reasonably expect an implantable composition in a variety

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of shapes depending on the particular intended use. Thus, in Preissman, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sheet shaped or screw shaped implantable composition.

Preissman and Okada are silent to the particular barium sulfate and polymer additive component percentages. It would also have been obvious to one of ordinary skill in the art to combine already known ingredients in particular weight percentages in order to optimize a composition. A practitioner would reasonably expect an optimized composition by way of routine experimentation. Thus, in Preissman and Okada, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular percentages claimed.

Conclusion

14. All claims have been rejected; no claims are allowed.

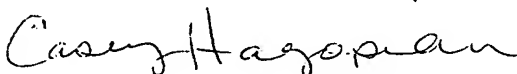
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

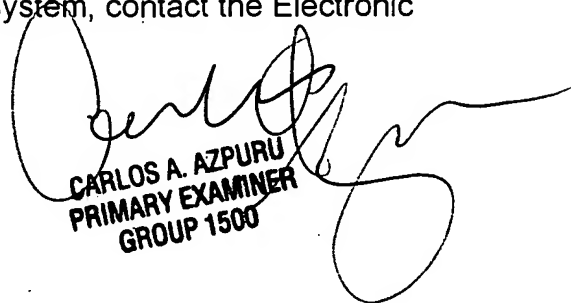
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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